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Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 3, 2000, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Nancy T. Cherry or Denise H. Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 3, 2000, the committee will hear an update on issues relating to transmissible spongiform encephalopathy and will review safety and efficacy data pertaining to a diphtheria/tetanus/acellular pertussis vaccine manufactured by Aventis Pasteur Ltd.

Procedure: On November 3, 2000, from 8:30 a.m. to 5:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 26, 2000. Oral presentations from the public will be scheduled between approximately 1:50 p.m.

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and 2:20 p.m., and between approximately 3:20 p.m. and 3:50 p.m. on November 3, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 26, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 3, 2000, from 8 a.m. to 8:20 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information.

(5 U.S.C. 552b(c)(4)). This portion will be closed to permit discussion of pending investigational new drug applications or pending product licensing applications.

FDA regrets that it was unable to publish this notice 15 days prior to the November 3, 2000, meeting of the Vaccines and Related Biological Products Advisory Committee. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Vaccines and Related Biological Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 10-17-00

October 17, 2000

Linda A. Suydam

Senior Associate Commissioner

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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